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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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12,442 10/12/01 WELLS

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12,442
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HM12/1022

EXAMINER

KNUSE, D

ART UNIT

PAPER NUMBER

1078

17

DATE MAILED:

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/055,145

Applicant(s)

Weeks et al

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 21-24, 36-39, 44, 47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 21, 24, 36, 39, 44, 47 and 48 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 5, 6, 22, 23, 37 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is in response to the Amendment and Response filed 30 July 2001 as Paper No. 16.
2. Claims 8-20, 25-35, 40-43, 45, 45 and 49 have been canceled as requested.
3. The newly executed Declaration of Inventorship filed 30 July 2001, for inventor Donald P. Weeks, has been entered into the file.
4. The Declaration of Dr. Donald P. Weeks, filed 30 July 2001, has been entered into the file.
5. It is noted that the drawings in the application are informal, and formal drawings will be required when the application is allowed.
6. The rejection of claims 21, 24 and 36 under 35 U.S.C. § 112, first paragraph, for written description is withdrawn.
7. The rejection of claims 39, 44, 47 and 48 under 35 U.S.C. § 112, first paragraph, for scope of enablement is withdrawn.
8. The rejection of claims 1-7, 21-24, 36-39, 44, 47 and 48 under 35 U.S.C. § 112, second paragraph, as indefinite is withdrawn.
9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

10. Claims 2, 3, 5 and 6 remain objected to, and 22, 23, 37 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening

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claims. This objection has been modified from the previous Office Action mailed 30 January 2001. The Weeks Declaration filed 20 July 2001 provides sufficient evidence, on pages 4-7, that Applicant was in possession of transgenic host cells, and plant cells, comprising a DNA sequence encoding a dicamba-degrading oxygenase having the amino acid sequence of SEQ ID NO: 4.

Claim Rejections - 35 USC § 112

11. Claims 1, 4, 7, 39, 44, 47 and 48 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 January 2001. Applicant's arguments filed 30 July 2001 have been fully considered but they are not persuasive.

Applicant argues that Applicant has taught a specific nucleic acid sequence (SEQ ID NO: 3) isolated from *Pseudomonas maltophilia*, strain DI-6, encoding a dicamba-degrading oxygenase (SEQ ID NO: 4), and that Applicant has also provided substantial additional disclosure in the application how to identify and isolate additional nucleic acid sequences encoding the same or different oxygenases (page 3 of the Response). The Examiner responds that in *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that

organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. Thus, Applicant has only provided sufficient written description of isolation of a dicamba-degrading oxygenase encoding gene from *Pseudomonas* spp.

Applicant argues that the present application discloses how to make and use transgenic plants producing active dicamba-degrading oxygenase (page 3 of the Response). The Examiner responds, the evidence provided in the Weeks Declaration on pages 5-7 only disclose transgenic plant expressing an active dicamba oxygenase enzyme encoded by a heterologous nucleotide sequence, the Weeks declaration does not provide evidence that Applicant was in possession of dicamba tolerant, transgenic plants at the time of the invention, or methods of using said transgenic plants.

12. Claims 39, 44, 47 and 48 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 January 2001. Applicant's arguments filed 30 July 2001 have been fully considered but they are not persuasive.

Applicant argues that Applicant has provided extensive guidance as to how to produce transgenic hosts, including plants, comprising a DNA sequence encoding a dicamba-degrading oxygenase. In addition, Applicant argues that the Weeks Declaration has provided evidence that Applicant has produced transgenic tobacco and *Arabidopsis* plants comprising DNA encoding the *P. maltophilia* DI-6 oxygenase and

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that the transgenic plants have been shown to express active oxygenase protein (page 4 of the Response). The Examiner responds, the state of the art at the time of Applicant's invention was such that producing transgenic plants having a specific phenotype, such as tolerance to dicamba as in the instant claims, remains unpredictable and required empiric evidence that the transgenic plant comprising a heterologous gene encoding a dicamba-degrading oxygenase confers dicamba tolerance when compared to a nontransformed plant. The Weeks Declaration states that transgenic tobacco and *Arabidopsis* plants were produced using the claimed isolated nucleotide sequence, and that active dicamba oxygenase enzyme activity was produced in said transgenic plants (page 7 of the Weeks Declaration). The Weeks Declaration does not provide evidence that said transgenic plants exhibited resistance to dicamba as in the instant claims.

13. Claims 1, 4, 7, 21, 24 and 36 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the DNA molecule of SEQ ID NO: 3, encoding the dicamba-degrading oxygenase of SEQ ID NO: 4, does not reasonably provide enablement for any DNA molecule encoding a dicamba-degrading oxygenase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 January 2001. Applicant's arguments filed 30 July 2001 have been fully considered but they are not persuasive.

Applicant argues that Applicant has provided substantial guidance as to how to obtain additional DNA molecules encoding dicamba-degrading oxygenases in addition to the one specific molecule. Applicant argues that techniques for identifying and isolating DNA molecules are well known in the art and that with the guidance provided by Applicant, it will now be a matter of routine experimentation to identify and isolate additional dicamba-degrading oxygenases, as exemplified in the Weeks Declaration (page 5 of the Response). The Examiner responds, the teachings of the instant application are limited to a dicamba oxygenase isolated from *Pseudomonas maltophilia*. The Weeks Declaration discloses an additional species that can use dicamba as a sole carbon source, *Sphingomonas* sp., and a review of bacterial taxonomy indicates that at least two *Pseudomonas* spp. have been reclassified as *Sphingomonas* species. Hence, although the teachings of the instant specification would not require undue experimentation to isolate other *Pseudomonas* dicamba oxygenase, given the state of the art at the time of Applicant's invention, it would require undue experimentation to isolate other dicamba oxygenases from the myriad of species known. The disclosed DNA sequence only showed 33.8% homology to other known oxygenases, and Applicant has not provided sufficient guidance as to what conserved encoded amino acid sequences or secondary structural features one of skill in the art would have to look for in order to identify the genus of dicamba oxygenases.

Conclusion

14. No claims are allowed.
15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3482.

David H. Kruse, Ph.D.
19 October 2001


GARY BENZION
PRIMARY EXAMINER